REMARKS:

In response to the Office Action mailed July 3, 2007, claims 22, 24, and 25 have been amended. Support for the amendment to claim 25 may be found in the specification, e.g., at page 6, lines 1-17 and at page 55, lines 5-10. No new matter has been introduced. Claims 1-10 and 21-30 remain pending.

In the Office Action, claim 22 was rejected under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis. In addition, claims 1-7 and 21-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,045,570 ("the Epstein reference") in view of U.S. Patent No. 6,162,240 ("the Cates reference"), and claims 8-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Cates reference and further in view of U.S. Patent No. 6,562,059 ("the Edwards reference"). Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the § 112 rejection, claim 22 has been amended to replace the "elongate occlusion member slidably disposed within the tubular member" with the "outer member being slidable through the tubular member." In addition, claim 24 has also been amended to replace "occlusion member." Support for the amendments may be found in claim 21, in the specification, e.g., at page 50, lines 1-15, and in the drawings, e.g., in FIGS. 1 and 9. No new matter has been introduced. Accordingly, this rejection should be withdrawn.

Turning to the Epstein reference, a closure device 21 is disclosed that includes a tubular member 22 including a main lumen 26 and a second lumen 27 communicating with a port 28 on the distal extremity 24. Col. 4, line 66 to col. 5, line 13. A closure assembly 32 is carried by the

distal extremity 24 of the tubular member 22 and is coupled to a deployment mechanism 33 for movement from a contracted to an expanded position. Col. 5, lines 28-33. The deployment mechanism 33 includes a push-pull wire 41 extending from the closure assembly 32 out the proximal extremity 23 of the tubular member 22 and connected to a handle assembly 44. Col. 5, line 65 to col. 6, line 10. The handle 44 is formed of a body 46 that is mounted on the proximal extremity 23 of the tubular member 22. Col. 6, lines 11-14. A button 47 is provided on the handle 44 that is slidably mounted in a slot 49 for moving the closure assembly 32 between the contracted and expanded positions. Col. 6, lines 14-24. Thus, the handle 44 does not include a piston slidably disposed within a chamber nor a reservoir filled with inflation media. Instead, the device merely includes a push-pull wire arrangement that moves the closure assembly 32 from the contracted to the expanded position.

The Epstein closure device 21 also includes biological sealant means 81 carried by the handle 44 and in communication with the second lumen 27 for delivering sealant components via the external port 28. Col. 7, lines 1215; col. 6, lines 28-43. During use, the closure device 21 is inserted into a sheath 111 in a puncture 106 extending to a vessel lumen 104 with the closure assembly 32 in the retracted position. Col. 9, lines 6-10; FIG. 5A. Once the distal extremity 24 of the tubular member 22 is exposed in the lumen 104, the sheath 111 is withdrawn, and the button 47 is retracted to expand the closure assembly 32. Col. 9, lines 10-23, 36-44. The tubular member 22 is then retracted ***with the closure assembly 32*** until the closure assembly 32 contacts the vessel wall 103 to form a seal. Col. 9, lines 54-60; FIG. 5B. A sealant 116 is then delivered through the second lumen 27 of the tubular member 22 and "through the exit port 28 which is adjacent the closure assembly 32." Col. 10, lines 35-44; FIG. 5C. The tubular member 22 is not

movable relative to the closure assembly 32, because it is fixed to the handle 44, which also prevents movement of the closure assembly 32 once expanded.

Once the sealant has assumed the desired state, the button 47 is moved within the slot 49 to retract the closure assembly 32 back into the tubular member 22, and the closure device 21 is removed from the puncture 106. Col. 11, lines 3-16. Thus, the Epstein reference does not teach or suggest a tubular member that is retractable proximally relative to an occlusion member. In contrast, the Epstein reference discloses a tubular member that remains fixed relative to a closure assembly, which is necessary because the tubular member is used to manipulate the closure assembly within a puncture and lumen.

Turning to the present claims, claim 1 recites an apparatus for sealing a puncture extending through tissue that includes a tubular member having a proximal end, a distal end sized for insertion into the puncture, and a lumen extending between the proximal and distal ends; an elongate occlusion member slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member; an expandable member on the occlusion member distal end; a delivery device coupled to the proximal end of the tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound into the tubular member lumen; and a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of the plunger to thereby disengage the lock, the retraction assembly being biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged.

The Epstein reference fails to disclose, teach, or suggest anything about a retraction assembly. In fact, the Epstein reference teaches against a retraction assembly that retracts a tubular member proximally relative to an occlusion member (let alone one that is biased to retract), because the tubular member 22 of the Epstein reference is necessarily coupled to the closure assembly 32, as explained above.

Turning to the Cates reference, because the Epstein reference teaches against using a retraction assembly that retracts a tubular member proximally relative to an occlusion member, ***it would not be obvious to combine the Cates reference with the Epstein reference***, even if the Cates reference disclosed such a retraction assembly. On this basis alone, claim 1 and its dependent claims are not obvious over the Epstein and Cates references.

Further, the Cates reference fails to disclose, teach, or suggest a retraction assembly, as claimed. Instead, the Cates reference discloses an applicator 14 that includes a housing assembly 35 including a cylindrical body 45 and a hand grip 46, an introducer assembly 36 including a barrel 50 to house a collagen plug 12, and a retraction assembly 38 that withdraws the introducer assembly 36 from around the collagen plug 12. Col. 6, lines 46-50, 60-61; col. 7, lines 1-3. The retraction mechanism 38 is attached to the barrel 50 to retract the barrel 50 into the body 45. Col. 7, lines 29-32. The retraction mechanism 38 includes ***"a manually engagable actuator member 61"*** that is intended ***"to be manually engaged and pulled back"*** toward the hand grip 46 pulling the barrel 50 to expose the collagen plug. Col. 7, lines 34-39 (emphasis added).

Thus, the Cates reference merely discloses an actuator member 61 that may be pulled by a user to disengage a ratchet pawl 62 and ***manually*** retract the barrel. The Cates reference does not teach or suggest a retraction mechanism that is ***biased to retract*** a tubular member proximally

relative to an occlusion member when a lock is disengaged. In direct contrast, the Cates reference discloses a manual actuator member that is ***biased to prevent retraction***.

As explained at col. 7, lines 44, the actuator member 61 is resiliently connected to the ring 60 so that the actuator member 61 is urged away from the ring 60. The actuator member 61 is provided with a ratchet pawl 62 that ***prevents*** the ring 60 from moving (because the actuator member 61 is urged away from the ring 60) ***until the actuator member 61 is pulled*** back toward the hand grip. 46. This action pivots the actuator member 61 and the ratchet pawl 62 out of engagement with the wall of the body 45 to release the barrel 50 for retraction. Nowhere does the Cates et al. reference state that the barrel 50 is biased to retract once the actuator member 61 and ratchet pawl 62 are out of engagement. Instead, the user must then pull the actuator member manually to retract the barrel 50. The disclosed bias merely causes the ratchet pawl 62 to automatically reengage when the actuator member 61 is released by the user, i.e., to lock the actuator member 61 and prevent further retraction.

Further, the Cates et al. reference fails to disclose, teach, or suggest a trigger that is activated by advancement of a plunger. Instead, the Cates reference discloses a manual actuator member 61 that may be pulled to disengage a ratchet pawl. Accordingly, even if the Cates reference could be properly combined with the Epstein reference (which Applicants do not concede), the combined teachings fail to render claim 1 and its dependent claims obvious.

The Edwards reference also fails to provide any additional teaching or suggestion absent from the Epstein and Cates references to render claim 1 obvious.

Similarly, claim 25 and its dependent claims are not obvious over the Epstein and Cates references. Claim 25 recites a retraction assembly coupled to the proximal end of the tubular

member and to the occlusion member, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activatable to disengage the lock, ***the retraction assembly being biased to automatically retract the tubular member proximally*** relative to the occlusion member when the lock is disengaged while delivering the sealing compound out the distal end of the tubular member ***to at least partially fill the puncture***. None of the cited references discloses, teaches, or suggests, a retraction assembly biased to automatically retract generally, nor a retraction assembly biased to automatically retract a tubular member proximally relative to an occlusion member when a lock is disengaged while delivering the sealing compound out the distal end of the tubular member specifically. Accordingly, claim 25 and its dependent claims are also not obvious over the cited references.

Finally, turning to claim 21, an apparatus for sealing a puncture extending through tissue is recited that includes an outer member comprising proximal and distal ends defining a longitudinal axis therebetween with an inflation lumen extending between the outer member proximal and distal ends, an expandable member comprising proximal and distal ends and having a variable length dimension, the proximal end of the expandable member being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior; an inner member slidably coupled to the outer member and comprising proximal and distal ends, the inner member distal end coupled to the expandable member distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the

proximal end of the expandable member when the expandable member is expanded and collapsed, respectively; and a housing on the proximal end of the outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir filled with inflation media and in fluid communication with the chamber, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands.

First, as explained above, the Epstein reference does not disclose, teach, or suggest a housing on the proximal end of an outer member that includes a) a piston slidably disposed within a chamber, b) a reservoir filled with inflation media and in fluid communication with the chamber, nor c) an actuator that directs inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands.

In direct contrast, the Epstein reference merely discloses a handle 44 that includes a button 47 slidable in a slot 49 for expanding and collapsing a closure assembly 32. Stated differently, the closure assembly 32 is expanded mechanically and not using fluid from a reservoir. There is no piston within a chamber of the handle, nor a reservoir filled with inflation media within the handle in fluid communication with the chamber. In fact, the Epstein reference

does not disclose, teach, or suggest anything about fluids within the handle 44 or otherwise within the device, other than the constituents of fibrin glue in syringes 86, 87.

The Cates et al. reference also fails to disclose, teach, or suggest a housing, as claimed. Instead, the Cates et al. reference merely discloses a syringe 26 that may be used to deliver inflation fluid into a tubular extension 31 that passes through the applicator to be connected to sealing assembly 11. Again, there is no piston within a chamber of the handle, nor a reservoir filled with inflation media within the handle in fluid communication with the chamber of the Cates et al. applicator. Accordingly, claim 21 and its dependent claims are also not obvious over the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: November 5, 2007

By _____
William A. English
Reg. No. 42,515
Attorneys for Applicants

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955